



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2012-N-0873]

Agency Information Collection Activities; Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the bar code label requirements for human drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Ila Mizrachi,  
Office of Information Management,  
Food and Drug Administration,  
1350 Piccard Dr.,  
PI50-400B,  
Rockville, MD 20850,  
301-796-7726,  
[ila.mizrachi@fda.hhs.gov](mailto:ila.mizrachi@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Bar Code Label Requirement for Human Drug and Biological Products--(OMB Control Number 0910-0537)--Extension

In the Federal Register of February 26, 2004 (69 FR 9120), we issued regulations that required human drug product and biological product labels to have bar codes. The rule required bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. The rule also required machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the National Drug Code number for the product. For blood and blood components, the rule specifies the minimum contents of the machine-readable information in a format approved by the Center for Biologics Evaluation and Research Director as blood centers have generally agreed upon the information to be encoded on the label. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Most of the information collection burden resulting from the final rule, as calculated in table 1 of the final rule (69 FR at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden

estimated in the final rule is now covered in other OMB- approved information collection packages for FDA. However, parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. Based on the number of exemption requests we have received, we estimate that approximately 2 exemption requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
201.25(d)	2	1	2	24	48

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.